

DETAILED ACTION

1. This action is set forth in response to the Applicant initiated telephonic interview on 5/26/09 with the Applicants' Attorney discussing the proposed claim amendment. An agreement was reached with regard to claim amendments during the interview, accordingly this action is set forth and the claims as amended were fully examined for patentability and found allowable as reflected in the Examiner's amendment.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Homer Faucett on May 26, 2009.

Please amend the claims as follows:

Cancel claims 18-19, 25-26, 29, 33-35, 37, 39-40, 43, 45-48, 65-66, and 86.

Claim 23. The method of claim 24 wherein the method comprises mutation scanning by comparing the melting curves.

Claim 24. A method of PCR analysis comprising the steps of:

mixing a dsDNA binding dye having a percent saturation of at least 90% with a sample comprising a selected target nucleic acid and primers configured for amplifying the selected target nucleic acid,

amplifying the target nucleic acid in the presence of the dsDNA binding dye, and

monitoring fluorescence of the dsDNA binding dye, wherein the monitoring step comprises

melting the amplified target nucleic acid to generate a melting curve,
repeating the mixing, amplifying, and generating a melting curve steps with at least one additional target nucleic acid, and comparing the melting curves,
wherein the melting curve for the selected target nucleic acid is selected as the standard and is plotted as stranded across melting temperatures and the melting curve for each additional target nucleic acid is plotted as a difference from the stranded across the melting curves.

Claim 27. The method of claim 24 further comprising the step of temperature shifting the melting curves by superimposing a portion of each curve.

Claim 28. The method of claim 27 further comprising the step of plotting the fluorescence difference between the temperature shifted curves, wherein the melting curve for the target nucleic acid is selected as the standard and is plotted as standard across melting temperatures and the melting curve for each additional target nucleic acid is plotted as a difference from the standard across the melting temperatures.

Claim 30. The method of claim 24 wherein the dye is selected from the group consisting of PO-PROTM-1, JO-PROTM-1, SYTO[®] 45, POPOTM-3, SYTO[®] 12, TOTOTM-3, SYTOX[®] Blue, YOYO[®]-3, SYTO[®] 43, SYTO[®] 11, G5, H5, D6, E6, P6, R6, Y6, Z6, and D8.

Claim 83. A method of PCR analysis comprising the steps of:
providing a mixture of a dsDNA binding dye having at least 90% saturation, a target nucleic acid, and primers configured for amplifying the target nucleic acid,
amplifying the target nucleic acid in the presence of the dsDNA binding dye,

monitoring fluorescence of the dsDNA binding dye,
generating a melting curve for the target nucleic acid,
normalizing magnitude differences of the melting curve,
repeating the providing, amplifying, generating and normalizing steps with at least one additional target nucleic acid,
comparing the magnitude difference normalized melting curves, and plotting the fluorescence difference between the magnitude difference normalized curves, wherein the melting curve of one selected target nucleic acid is selected as the standard and is plotted as standard across melting temperatures and the melting curve for each additional target nucleic acid is plotted as a difference from the standard across the melting temperatures.

Claim 84. A method of PCR analysis comprising the steps of:

providing a mixture of a dsDNA binding dye having at least 90% saturation, a target nucleic acid, and primers configured for amplifying the target nucleic acid,
amplifying the target nucleic acid in the presence of the dsDNA binding dye,
monitoring fluorescence of the dsDNA binding dye,
generating a melting curve for the target nucleic acid,
normalizing magnitude differences of the melting curve,
repeating the providing, amplifying, generating and normalizing steps with at least one additional target nucleic acid,
comparing the magnitude difference normalized melting curves, and plotting the fluorescence difference between the magnitude difference normalized curves, wherein the melting curve of one selected target nucleic acid is selected as the standard and is plotted as

standard across melting temperatures and the melting curve for each additional target nucleic acid is plotted as a difference from the standard across the melting temperatures wherein the standard is plotted as zero across all melting temperatures.

Claim 85. The method of claim 83 further comprising the step of temperature shifting melting curves by superimposing a portion of each curve and plotting the fluorescence difference between the temperature shifted curves, wherein the melting curve for the target nucleic acid is selected as the standard and is plotted as standard across melting temperatures and the melting curve for each additional target nucleic acid is plotted as a difference from the standard across the melting temperatures.

Reasons for Allowance:

4. The following is an examiner's statement of reasons for allowance:

Claims 20, 23-24, 27-28, 30, 49-51, 53, 55-58, 61, 83-85 are allowed.

The present invention is drawn to a method of PCR analysis comprising amplifying a target nucleic acid in the presence of a dsDNA binding dye having at least 90% saturation, monitoring, fluorescence of the dsDNA binding dye by generating melting curve, normalizing melting curve and comparing the melting curve for the target nucleic acid with the melting curve generated with at least one additional target nucleic acid, wherein the melting curve for the target nucleic acid is plotted as a standard and the melting curve for each additional target nucleic acid is plotted as a difference from the standard. The closest prior art Elenitoba-Johnson (US6,346,386) teach said method, however the closest prior art does not use of a dsDNA binding dye having at least 90% saturation and comparing magnitude-difference-normalized melting curves as required

by the instant amended claims. Thus the instant invention was not taught or obvious over the closest prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

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